K102008

# 510(k) Summary



## *A. Device Name*

| | |
|---|---|
| Proprietary Name | Glidesheath |
| Classification Name | Catheter Introducer (as per 870.1340) |
| Common Name | Introducer Sheath |
| Product Code | DYB |

## *B. Intended Use*

The Glidesheath is used to facilitate placing a catheter through the skin into a vein or artery including but not limited to the radial artery.

The Entry Needle is an accessory device which is used to gain access to the vein or artery including but not limited to the radial artery, for placement of the Mini Guide Wire.

The Mini Guide Wire is an accessory device which is used for placement of the sheath into the vein or artery including but not limited to the radial artery.

## *C. Device Description*

The Glidesheath is comprised of an introducer sheath and a dilator. The Glidesheath is coated with a hydrophilic coating to reduce the frictional resistance of the sheath when inserting or removing the sheath from the patient's blood vessel. The Sheath and Dilator contain bismuth, making these devices visible under fluoroscopy.
The Glidesheath is used to facilitate placing a catheter through the skin into a vein or artery including but not limited to the radial artery.

The Entry Needle is an accessory device which is used to gain access to the vein or artery including but not limited to the radial artery, for placement of the Mini Guide Wire.

The Mini Guide Wire is an accessory device which is used for placement of the sheath into the vein or artery including but not limited to the radial artery. The Guide Inserter which is attached to the Mini Guide Wire holder is used to straighten out the wire.

Accessories to the Glidesheath are the metal entry needle and the mini guide wire. Both the metal entry needle and the mini guide wire are packaged with the Glidesheath in a pouch prior to sterilization.

### *D. Principle of Operation / Technology*

The Glidesheath and its accessories are operated manually or by a manual process.

Using the Guide Inserter to straighten the Mini Guide Wire, the Mini Guide Wire is inserted through a cannula placed in the patient's blood vessel. The Glidesheath is then inserted over the Mini Guide Wire and into the blood vessel. The Mini Guide Wire is then withdrawn from the vessel. The Dilator maintains the integrity of the Sheath and dilates the blood vessel while the Glidesheath is being placed into the vessel. The Dilator can be removed and an appropriate catheter can then be inserted.

### *E. Design / Materials*

| | Current Glidesheath | Predicate Glidesheath (K082644) |
|---|---|---|
| **Sheath** | | |
| Tubing | Ethylene-Tetrafluoroethylene (ETFE) copolymer containing bismuth trioxide | Ethylene-Tetrafluoroethylene (ETFE) copolymer containing bismuth trioxide |
| Hydrophilic Coating | Dimethyl acrylamide-glycidyl methacrylate copolymer | Dimethyl acrylamide-glycidyl methacrylate copolymer |
| Housing | Polypropylene | Polypropylene |
| Valve | Silicone Rubber | Silicone Rubber |
| Cap | Polypropylene | Polypropylene |
| Caulking Pin | Stainless Steel | Stainless Steel |
| Sheath Support | Styrene elastomer | Styrene elastomer |
| Side Tube | Polybutadiene | Polybutadiene |
| **Three-way stopcock** | | |
| Holder | Polycarbonate | Polycarbonate |
| Cock | Polyethylene | Polyethylene |
| Luer Cap | Polypropylene | Polypropylene |
| **Dilator** | | |
| Tube | Polypropylene containing bismuth subcarbonate | Polypropylene containing bismuth subcarbonate |
| Hub | Polypropylene | Polypropylene |

| | Current Glidesheath | Predicate Glidesheath (K082644) | |
|---|---|---|---|
| Caulking Pin | Stainless Steel | Stainless Steel | |
| **Mini Guide Wire** | | Plastic Option | Metallic Option |
| Spring | Palladium | Polyurethane/tungsten with silicon coating | Stainless Steel |
| Core | Nickel-Titanium alloy | Nickel-Titanium alloy | Stainless Steel |
| **Inserter** | Polyethylene | Polyethylene | |
| **Entry Needle** | | | |
| Needle Hub | Polycarbonate | Polycarbonate | |
| Cannula | Stainless Steel | Stainless Steel | |
| Cap | Polypropylene | Polycarbonate | |

Both devices have similar parts which function in the same manner. Differences in materials between the Glidesheath device covered in this submission and the predicate device, cleared under K082644, raise no new issues of safety or effectiveness.

***F. Specifications***

| | Current Glidesheath | Predicate Glidesheath (K082644) |
|---|---|---|
| Sheath Size | 5 & 6 French | 4, 5 & 6 French |
| Sheath Length | 10 cm | 10 – 25 cm |
| Sheath Hydrophilic Coating | 10 cm (entire length of shaft) | 10 – 25cm (entire length of shaft) |
| Dilator Length | 15.5 cm | 15.5 – 30.5 cm |
| Guide Wire OD | 0.021" | 0.021" – 0.038" |
| Guide Wire Length | 45 cm | 10 – 180 cm |
| Entry Needle: Size | 21G | 20 G – 21 G |
| Entry Needle Length | 1.5" | 1.5" |
| IV Catheter | Not Available | 16 G – 22 G |
| IV Catheter Length | Not Available | 1" – 2.5" |
| Scalpel | Not Available | Available |
| Syringe | Not Available | Available |
| Obturator | Not Available | Available |

All specifications of the Glidesheath included in this submission are within the specification ranges of the predicate device. The comparison of specifications raises no new issues of safety or effectiveness.

*G. Performance*

The Glidesheath successfully passed all of the following performance tests:

Needle

- Needle surface free from defects
- Needle OD
- Needle length
- Needle ID
- Needle hub conical entry angle
- Bevel indicator visibility
- Bevel indicator position
- Needle to hub joint strength
- Gauge Luer taper
- Liquid leakage from fitting assembly under pressure
- Air leakage into the fitting assembly during aspiration
- Separation force of fitting assembly
- Unscrewing torque of fitting assembly
- Ease of assembly
- Resistance to overriding
- Stress cracking
- Corrosion resistance

Guide Wire

- Guidewire surface free from defects
- Tip buckling test
- Test for resistance of guidewires to damage by flexing
- Test for fracture of guidewires
- Test for distal tip retention
- Guidewire OD
- Guidewire length
- Test for corrosion resistance

Dilator

- Dilator surface free from defects
- Dilator tip ID
- Dilator to hub joint strength

Sheath

- Sheath surface free from defects
- Sheath tip ID
- Sheath to housing joint strength

- Housing to cap joint strength

Inserter

- Guidewire inserter surface free from defects

System

- System use in model

## *H. Biocompatibility and Sterilization*

The Glidesheath is classified as Externally Communicating Devices, Circulating Blood, Limited Contact (≤ 24h). Results of the testing demonstrate that the blood contacting materials are biocompatible.

Blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". The Glidesheath successfully passed all of the following biocompatibility tests:

- Physicochemical Profile
- Cytotoxicity
- Sensitization
- Acute Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemolysis
- Thromobogenicity
- Complement Activation Assay
- Unactivated Partial Thromboplastin Time Assay
- In Vitro Hemolysis
- Genotoxicity
- Pyrogen Study
- Extractable Metals and Acidity/Alkalinity (needle assembly)

Sterilization conditions have been validated according to ANSI / AAMI / ISO 11135, *Sterilization of Health Care Products– Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* to provide a Sterility Assurance Level (SAL) of 10-6.

## *I. Substantial Equivalence*

The performance of the Glidesheath in this submission is substantially equivalent to the performance of the predicate device. The equivalence was shown through

comparison of component materials and specifications, performance and biocompatibility testing and sterilization validation.

The Glidesheath is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the predicate device the Glidesheath, cleared under K082644. Differences between the devices do not raise any significant issues of safety or effectiveness.

## *J. Submitter Information*

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Date Prepared: July 2, 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Terumo Medical Corporation
c/o Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

JUL 21 2010

Re: K102008
Trade/Device Name: Glidesheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Introducer
Regulatory Class: Class II (Two)
Product Code: DYB
Dated: July 15, 2010
Received: July 16, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102008

# Indications for Use

510(k) Number (if known): K102008

Device Name: Glidesheath™

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JUL 21 2010

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Richardson

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102008